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(54) Title: SURGICAL IMPLANT

(57) Abstract: A surgical implant suitable for treatment of hernias is provided. The implant comprises a mesh having a residual maximum mass density of 50g/m². The mesh comprises strands forming spaces and the strands comprise filaments forming pores. The spaces and pores are sized to minimise foreign body mass for implantation and to encourage integration of the implant. The mesh may be delivered using Dual Phase Technology™ for ease of handling, cutting and placement. The Dual Phase Technology™ may include encapsulation or coating with hydrogel.

1 **"Surgical Implant"**

2

3 The present invention relates to the treatment of a
4 hernia such as a uterovaginal prolapse and, in
5 particular, to a surgical implant for use in such
6 treatment and to a related surgical procedure and
7 device.

8

9 A hernia is basically a defect resulting in the
10 protrusion of part of an organ through the wall of a
11 bodily cavity within which it is normally contained.
12 For example, a fairly common and well known type of
13 hernia is a defect in the lower abdominal wall
14 resulting in a sac which may contain a portion of
15 the intestine protruding through the abdominal wall.
16 This is referred to as an inguinal hernia.
17 Similarly, a defect in the abdominal wall after
18 surgery is referred to as an incisional hernia.
19 Another type of hernia is a defect in the pelvic
20 floor or other supporting structures resulting in a
21 portion of the uterus, bladder, bowel or other
22 surrounding tissue protruding through, e.g., the

1 vaginal wall. This is usually referred to as
2 uterovaginal prolapse.

3

4 A common way of treating hernias is to repair the
5 defect by sutures, whether or not the hernial sac is
6 also sutured or repaired, in order that the
7 protruding organ is contained in its normal
8 position. As the defect generally comprises a
9 weakening and attenuation leading to parting of
10 tissues in a fascial wall, it is usually necessary
11 to apply tension to the sutures in order to close
12 the parted tissues. Thus, the fascial wall is
13 generally pinched or tensioned around the area of
14 the defect in order to close the parted tissues.

15

16 This treatment is generally effective, but does have
17 some inherent problems. In particular, the pinching
18 or tensioning of tissue around the defect can lead
19 to discomfort and/or recurrence of the hernia.

20 Additionally, in the case of uterovaginal prolapse,
21 such pinching or tensioning of the vaginal wall
22 almost inevitably results in anatomical distortion
23 (such as narrowing of the vaginal cavity) with
24 consequential pain and quality of life implications
25 for the patient and relatively high recurrence
26 and/or complication rates.

27

28 In order to address these problems, in the case of
29 inguinal hernia repair, it has been suggested to
30 make use of a surgical implant to overlay or close
31 the weakened and parted tissues without the need to
32 pinch or tension the surrounding tissue of the

1 fascia. Such surgical implants generally comprise
2 meshes and are now widely used in inguinal hernia
3 repair. Meshes may be applied subcutaneously (i.e.
4 under the skin), internally or externally of the
5 abdominal wall and may be either absorbable or non-
6 absorbable depending on the nature and severity of
7 the particular defect being treated. Meshes may be
8 applied in combination with sutures to hold the mesh
9 in place or, alternatively, with sutures that close
10 the parted tissues as in a "non-mesh" technique.
11 Meshes are usually applied in open surgical
12 procedures, although they may sometimes be applied
13 in laparoscopic surgical procedures.

14
15 A typical mesh for an inguinal hernia repair
16 comprises woven or knitted polypropylene such as
17 Marlex® or Prolene®. Such meshes have a number of
18 desirable properties that make them effective for
19 use in hernia repair. For example, they are made of
20 materials that are suitably inert so as to be less
21 likely to cause adverse reactions when implanted in
22 the body. Furthermore, they are mechanically
23 strong, cheap, easily sterilisable and easy to work
24 with.

25
26 However, conventional meshes have a number of
27 inherent problems. For example, fistula or sinus
28 (i.e. abnormal passages between internal organs or
29 between an internal organ and the body surface) can
30 develop as a result of a mesh being implanted and
31 left inside the body. More generally, the placement
32 of a foreign body subcutaneously can also lead to

1 inflammation or infection. Similarly, edge extrusion
2 (i.e. the erosion of body tissue around the edge of
3 the mesh) can occur. Nevertheless, overall, the use
4 of meshes is generally considered to be beneficial
5 in the treatment of incisional and inguinal hernias.
6

7 It has also been suggested to use meshes in the
8 treatment of uterovaginal prolapse. Meshes that
9 have been proposed for use in the repair of
10 uterovaginal prolapse are similar to those that are
11 used for the repair of inguinal hernia and such
12 like. However, there is concern that the above
13 mentioned problems with the use of meshes are
14 greater when a mesh is placed in the vaginal wall as
15 this tissue is generally thin only just below the
16 surface and therefore more prone to adverse
17 reactions. Furthermore, the placement of a foreign
18 body close to the rectum and urinary tract may
19 increase the risk of infection, inflammation,
20 erosion, fistula or translocation. Thus, it is a
21 relatively widespread view that the use of meshes in
22 the treatment of vaginal prolapse is less desirable
23 than in the treatment of other hernias.

24
25 Nevertheless, as the use of meshes to treat
26 uterovaginal prolapse can avoid anatomical
27 distortion and the above mentioned problems related
28 to this, the Applicant considers there are
29 significant benefits in the use of meshes in the
30 treatment of uterovaginal prolapse should it be
31 possible to mitigate the problems associated with
32 mesh treatment.

1 The applicant has recognised that there are a number
2 of specific features of conventional meshes that
3 exacerbate the problems of fistula, sinus, edge
4 extrusion, infection etc., particularly when these
5 meshes are implanted in the vaginal wall. The
6 Applicant has therefore realised that it is possible
7 to provide a surgical implant that has the benefits
8 of mesh treatment, i.e. the avoidance of anatomical
9 distortion and its related problems, and also
10 minimises the above mentioned problems.

11

12 One specific problem with conventional meshes that
13 the Applicant has recognised is that they have
14 jagged or rough edges. The rough edges arise as
15 conventional meshes are generally formed from sheets
16 of multiple woven or intersecting fibres or strands.
17 When the meshes are cut to size in manufacture or
18 prior to fitting, the stray ends of the fibres or
19 strands are left extending from the edge of the
20 mesh, particularly where the edge is curved. In
21 other words, the perimeter of the mesh comprises the
22 spaced ends of the fibres or strands and is not
23 smooth. It is thought that the jagged rough nature
24 of the edges of the implant increases the likelihood
25 of extrusion of the edge of the mesh *in situ*.

26

27 Conventional meshes are generally unnecessarily
28 strong and substantial for use in the vaginal wall
29 and of significant mass. This results in an
30 unnecessary excess of foreign body material in the
31 vaginal wall, increasing the risks associated with
32 the placement of foreign bodies inside the human

1 body, such as the risk of infection. Likewise, the
2 bulk of such meshes can undesirably result in
3 discomfort for the patient as the mesh can often be
4 felt when in position. This is of particular
5 concern when a mesh is placed in sensitive vaginal
6 tissues or near to bowel or bladder.

7
8 A further disadvantage of the meshes presently used
9 to treat hernias relates to pore size. The pore
10 size of meshes in use is unphysiological and does
11 not encourage acceptance of the implant in the body.
12

13 It is a aim of the present invention to overcome
14 problems associated with existing meshes used to
15 treat hernias.
16

17 According to the present invention there is provided
18 a surgical implant suitable for treatment of
19 hernias, the implant comprising a mesh having a
20 residual maximum mass density of 50g/m².
21

22 Preferably the maximum mass density is less than
23 30g/m². More preferably the maximum mass density is
24 less than 25g/m².
25

26 By minimising mass density of a mesh for use in
27 treating hernias the advantages of using a mesh are
28 still apparent whereas the disadvantages are
29 lessened in that jagged and rough edges are
30 minimised as is the risk of infection. The residual
31 mass density is the mass density of the mesh after
32 implantation.

- 1 Preferably the surgical implant mesh comprises strands and includes major spaces and pores.
- 2
- 3
- 4 The strands of the mesh may be formed by at least two filaments, the major spaces formed between the strands providing the surgical implant with the necessary strength, the filaments arranged such that pores are formed in the strands of the mesh.
- 5
- 6
- 7
- 8
- 9
- 10 Alternatively the strands may be formed by monofilaments which form loops which give rise to the pores.
- 11
- 12
- 13
- 14 Preferably strands are spaced by wider distance than the fibres or filaments of conventional meshes used in hernia repair.
- 15
- 16
- 17
- 18 Preferably the strands are spaced apart to form major spaces of between 1 to 10 mm.
- 19
- 20
- 21 More preferably the strands are spaced apart to form major spaces of between 2 to 8 mm.
- 22
- 23
- 24 The use of mesh having strands spaced between 1 to 10 mm apart has the advantage of reducing the foreign body mass that is implanted in the human body. Only sufficient tensile strength to securely support the defect and tissue being repaired is provided by the mesh.
- 25
- 26
- 27
- 28
- 29
- 30
- 31 It is desirable that the mesh of the present invention has a mass of between one tenth (1/10th)
- 32

1 and one hundredth (1/100th) that of a conventional,
2 e.g. Prolene®, mesh of the same surface area. The
3 mesh of the invention therefore avoids the
4 unnecessary bulk of conventional meshes.

5

6 More specifically it is preferred that the mass
7 density is less than 50g/m², more preferably less
8 than 30g/m and most preferably less than 20g/m².
9 It is also preferred that the strands of the mesh of
10 the present invention are narrower than those of
11 meshes of the prior art.

12

13 Preferably the strands have a diameter of less than
14 600µm.

15

16 In one embodiment the strands are arranged to form a
17 diamond net mesh.

18

19 In an alternative embodiment the strands are
20 arranged to form a hexagonal net mesh.

21

22 The strands and filaments are preferably warp knit.

23

24 In an alternative embodiment the strands are
25 arranged to form a net mesh with suitable tensile
26 strength and elasticity.

27

28 Preferably the strands are arranged to form a net
29 mesh which has isotropic or near isotropic tensile
30 strength and elasticity.

31

1 Preferably the filaments have a diameter of between
2 0.02 to 0.15 mm.

3

4 More preferably the filament of the mesh is of a
5 diameter 0.08 to 0.1 mm.

6

7 This likewise has the advantage of reducing the
8 overall bulk of the implant, and hence the amount of
9 material retained in the human body.

10

11 Particular meshes which are embodiments of the
12 present invention include warp knit diamond or
13 hexagon net diamond net meshes. Four particular
14 embodiments are set out below.

15

16 In two particular embodiments wherein the filaments
17 are formed from polypropylene having a diameter of
18 0.07 - 0.08mm wherein the strands are spaced to form
19 spaces of either 2mm or 5mm.

20

21 Alternatively, filaments are formed from polyester
22 having a diameter of 0.09mm wherein the strands are
23 spaced to form spaces of 5mm.

24

25 Alternatively, filaments are formed from polyester
26 having a diameter of 0.05 - 0.07mm wherein the
27 strands are spaced to form spaces of 2mm.

28

29 As the surgical implant is comprised of narrow
30 members arranged to be spaced by relatively wide
31 gaps, major spaces, tissue may be slow to grow into
32 the mesh. It is desirable for the mesh to have

1 means for promoting tissue ingrowth. More
2 specifically, it is desirable to provide pores in
3 the strands of the mesh to aid tissue ingrowth and
4 to which tissue may more easily adhere.

5

6 Preferably two filaments are interwoven/knitted to
7 produce strands of the mesh comprising pores.

8

9 Alternatively at least three filaments are
10 interwoven/knitted to produce strands of the mesh
11 comprising pores.

12

13 For manufacturing reasons it is preferred that two
14 filaments are used to form the pores in the strands
15 of the mesh which aid tissue ingrowth, however if
16 the one filament could be suitably knotted or
17 twisted to form pores of suitable dimensions it is
18 clear that this could be used to similar effect to
19 form the strands of the mesh.

20

21 Preferably the pores in the strands are of between
22 50 to 200 μm in diameter.

23

24 More preferably the pores are of between 50 to 75 μm
25 in diameter.

26

27 This is important in enabling efficient fibroblast
28 throughgrowth and ordered collagen laydown in order
29 to provide optimal integration into the body. This
30 is discussed in detail in copending Patent
31 Application No PCT/GB01/04554.

32

1 Rings or loops of material comprising pores of
2 between 50 to 200 μm may be adhered to or formed on
3 the strands of the mesh to provide pores.

4

5 As mentioned above, reducing the mass of the mesh
6 has distinct advantages in relation to the
7 suitability of the mesh for implantation in the
8 body, i.e. the reduction of foreign body mass and
9 improving the comfort of the patient. However, the
10 handling characteristics of such a mesh, e.g. the
11 ease with which a surgeon can manipulate and place
12 the surgical implant in its desired location in the
13 body, can be poor in some circumstances. More
14 specifically, a mesh having narrow members or
15 strands that are widely spaced will inevitably be
16 somewhat flimsy and lacking in rigidity compared to
17 conventional meshes.

18

19 Ideally the implant should be formed from materials
20 or uses technologies which provide the implant with
21 Dual Phase Technology™, such that it has suitable
22 surgical handling characteristics and is also of
23 minimal mass and suited for implantation in the
24 body. The implant may be formed from a range of
25 materials to provide it with Dual Phase
26 Technology™.

27 The term Dual Phase Technology™ refers to a means
28 to provide temporary substance to the mesh.

29 Depending on the type of Dual Phase Technology™
30 employed the benefits imported, in addition to
31 allowing minimal residual mesh mass may include
32 assisting the mesh to be handled and cut, minimising

1 the effect of rough edges, assisting placing the
2 mesh in position and providing tackiness to assist
3 in holding the mesh in position on implantation,
4 thus minimising or negating the need for any
5 additional fixation by suturing or adhesion.

6

7 In a preferred embodiment of the invention having
8 improved handling characteristics, the implant
9 therefore has an absorbable coating.

10 Preferably this coating encapsulates the mesh of the
11 surgical implant.

12

13 Alternatively this coating is applied to at least
14 one face of the mesh.

15

16 The coating, covering or layer of absorbable
17 material stiffens and adds bulk to the mesh such
18 that it is easier to handle.

19

20 As the coating, covering or layer is absorbable, it
21 is absorbed by the body after implantation and does
22 not contribute to the foreign body mass retained in
23 the body. Thus, the advantages of a surgical
24 implant having minimal mass are retained.

25

26 Preferably the coating, covering a layer absorbs
27 within 48 hours following implantation.

28

29 The coating, covering or layer may comprise any
30 suitable soluble and biocompatible material.

31

1 Suitable hydrogel materials can be obtained from
2 First Water in the UK. A typical hydrogel being
3 developed for use in this application is known as
4 FIRST PHASE™ or PHASE 1™.

5

6 The absorbable material may be a soluble hydrogel
7 such as gelatin,

8

9 Alternatively the absorbable material is a starch or
10 cellulose based hydrogel.

11

12 In a further alternative the absorbable material is
13 an alginate.

14

15 In a further alternative the absorbable material may
16 contain hyaluronic acid.

17

18 The coating, covering or layer may have any
19 thickness or bulk that provides the surgical implant
20 with suitable handling characteristics.

21

22 Preferably, the coating is a sheet with a thickness
23 greater than that of the mesh.

24

25 Suitable handling characteristics may also be
26 provided to the mesh by a range of other methods.
27 The surgical implant may comprise a mesh and a
28 backing strip the backing strip releasably
29 attachable to the mesh.

30

31 The backing strip may be formed from a range of
32 materials including plastics.

1 The surgical implant may be releasably attachable to
2 the backing strip by adhesive.

3

4 The releasable attachment of a backing strip to the
5 mesh provides a more substantial and less flexible
6 surgical implant that is more easily handled by a
7 surgeon. Following suitable placement of the
8 surgical implant the backing strip can be removed
9 from the surgical implant, the surgical implant
10 being retained in the body and the backing material
11 being removed by the surgeon. The surgical implant
12 can therefore benefit from reduced mass while still
13 providing characteristics required for surgical
14 handling.

15

16 In a further alternative the strands of the mesh of
17 the surgical implant are comprised of bicomponent
18 microfibres.

19

20 Preferably the bicomponent microfibres comprise a
21 core material and surface material.

22

23 The composite or biocomponent fibres preferably
24 comprise a nonabsorbable or long lasting absorbable
25 core and a shorter lasting absorbable surface
26 material.

27

28 Whereas any licenced materials may be used, suitable
29 materials presently available include polypropylene
30 for the core and polylactic acid or polyglycolic
31 acid for the surface materials.

1 Alternativley the bicomponent microfibres comprise
2 an material which is rapidly absorbed by the body
3 and a material which is not absorbed for a suitable
4 longer period of time.

5

6 Preferably the surface material is capable of being
7 absorbed by the body in a period of less than 48
8 hours.

9

10 Preferably the core material is capable of remaining
11 in the body for a period of time sufficient to
12 enable tissue ingrowth.

13

14 The surface material of the bicomponent microfibres
15 or a portion of the composite polymers present
16 during the insertion and placement of the surgical
17 implant provides the surgical implant with
18 characteristics required for surgical handling.

19

20 Following a period of insertion in the body, the
21 surface material of the bicomponent microfibre is
22 absorbed by the body leaving behind the reduced
23 foreign mass of the core material of the strands of
24 the mesh.

25

26 It is preferred that the surface material of the
27 bicomponent microfibre is absorbed by the body
28 within a number of hours such that only a core
29 portion is left in the body for an extended length
30 of time. Typically materials presently available
31 which could be used to form the microfibres are
32 absorbed by the body over a period of days or weeks.

1 The filaments of the mesh comprise a plastics or
2 synthetic material.

3

4 Preferably the filaments of the mesh comprise of
5 polypropylene or polyester.

6

7 Alternatively the filaments of the mesh comprise an
8 absorbable material.

9

10 It can be appreciated that filaments which comprise
11 in part of absorbable material would allow better
12 surgical handling, but would enable the implant to
13 also have minimal mass following implantation in the
14 body.

15

16 Preferably the surgical implant comprises material
17 that has memory.

18

19 Preferably the surgical implant has memory which
20 urges the surgical implant to adopts a flat
21 conformation.

22

23 Preferably the implant has a generally curved
24 perimeter, i.e. to have few or no corners or apexes,
25 as sharp corners increase the likelihood of edge
26 erosion and infection. The specific shape will,
27 however, vary according to the use to which the
28 implant is to be put.

29

30 Due to the variety of sizes of such defects, and of
31 the various fascia that may need repair by the
32 implant, the implant may have any suitable size,

1 Preferably the surgical implant is of width between
2 1 cm to 10 cm and of length between 1 cm to 10 cm.

3

4 It may be desirable to provide a variety of implants
5 having different sizes in order that a surgeon can
6 select an implant of suitable size to treat a
7 particular patient. This allows implants to be
8 completely formed before delivery, ensuring, for
9 example, that the smooth edge is properly formed
10 under the control of the manufacturer. The surgeon
11 would have a variety of differently sized (and/or
12 shaped) implants to hand and select the appropriate
13 implant to use after assessment of the patient.

14

15 Typically an anterior uterovaginal prolapse is
16 ellipse shaped or a truncated ellipse whereas a
17 posterior prolapse is circular or ovoid in shape.

18

19 Accordingly the implant shape may be any one of
20 elliptical or truncated ellipse, round, circular,
21 oval, ovoid or some similar shape to be used
22 depending on the hernia or polapse to be treated.

23

24 Different shapes are suitable for repairing
25 different defects in fascial tissue and thus by
26 providing a surgical implant which can be cut to a
27 range of shapes a wide range of defects in fascial
28 tissue can be treated.

29

30 Preferably the mesh can be cut to any desired size.
31 The cutting may be carried out by a surgeon or nurse
32 under sterile conditions such that the surgeon need

1 not have many differently sized implants to hand,
2 but can simply cut a mesh to the desired size of the
3 implant after assessment of the patient. In other
4 words, the implant may be supplied in a large size
5 and be capable of being cut to a smaller size, as
6 desired.

7

8 In this regard, whilst the surgical implant of the
9 invention is particularly useful for the repair of
10 uterovaginal prolapse, it may be used in a variety
11 of surgical procedures including the repair of
12 hernias.

13

14 Preferably the surgical implant is suitable for use
15 in the treatment of hernias including incisional and
16 inguinal hernias and/or for the treatment of
17 uterovaginal prolapse.

18

19 More broadly, the Applicant has therefore recognised
20 that the implant can have any shape that conforms
21 with an anatomical surface of the human or animal
22 body that may be subject to a defect to be repaired
23 by the implant.

24

25 As discussed a disadvantage of the meshes used in
26 hernia repair is that they have jagged or rough
27 edges. Due to the wide spacing between strands of
28 the mesh described above and the small diameter of
29 the filaments, the edge problems are mitigated to an
30 extent by the present invention.

31

1 To further reduce edge problems it would be
2 preferable if a mesh had a circumferential member
3 which extends, in use, along at least part of the
4 perimeter of the implant to provide a substantially
5 smooth edge.

6

7 In other words, the mesh has at least one
8 circumferential member (i.e. fibre, strand or such
9 like) that extends around at least part of its
10 circumference.

11

12 Preferably at least part of the perimeter of the
13 implant is defined by the circumferential member,

14

15 Alternatively at least part of the perimeter of the
16 implant is defined by more than one circumferential
17 member, at the edge of the mesh.

18

19 The edge of the mesh, and hence the perimeter of the
20 implant, can therefore be generally smooth and this
21 has significant advantages over conventional
22 surgical meshes. Specifically, the Applicant has
23 recognised that an implant having a smooth edge is
24 less likely to cause edge extrusion or erosion.

25

26 Any amount of the perimeter of the implant may be
27 defined by the circumferential member(s).

28

29 However, in order to maximise the benefits of the
30 implant of the invention, it is preferable that at
31 least 50% of the perimeter of the implant is defined
32 by the circumferential member(s)..

1 More preferably at least 80% of the perimeter of the
2 implant is defined by the circumferential member(s).

3

4 Most preferably 100% of the perimeter of the implant
5 is defined by the circumferential member(s).

6

7 The majority or the whole of the perimeter of the
8 mesh being smooth minimises the risk of a rough edge
9 causing edge erosion or infection.

10

11 The circumferential member(s) may be arranged in one
12 of a variety of ways to provide the smooth edge or
13 perimeter.

14

15 Preferably the circumferential members are arranged
16 such that they each follow the edge of a desired
17 shape of the surgical implant, the perimeter of the
18 implant formed from as few members as possible.

19

20 This simplifies the construction of the mesh, which
21 is desirable not only for manufacture, but also
22 because simpler structures are less likely to have
23 defects which might be problematic after
24 implantation.

25

26 Preferably the perimeter of the mesh is defined, in
27 use, by one circumferential member.

28

29 Preferably the mesh has a plurality of
30 circumferential members arranged at different radial
31 locations.

32

- 1 In order to provide an implant of given dimensions,
2 the periphery of the mesh outward of the desired
3 circumferential member is cut away such that one or
4 more selected circumferential members form the
5 perimeter of the implant as desired.
- 6
- 7 More preferably, the circumferential members are
8 arranged concentrically.
- 9
- 10 A concentric arrangement of a plurality of
11 circumferential members conveniently allows
12 maintenance of the shape of the implant for
13 different sizes of implant and provides the mesh
14 with an even structure.
- 15
- 16 The remainder of the structure of the mesh may take
17 a variety of forms.
- 18
- 19 The circumferential members can be arranged to join
20 with one another in order to form an integral mesh.
- 21
- 22 Alternatively the mesh may additionally comprise
23 transverse members which extend across the
24 circumferential members joining the circumferential
25 members.
- 26
- 27 The transverse members may extend radially from a
28 central point to the perimeter of the implant.
- 29
- 30 Alternatively, the transverse members may extend
31 toward the perimeter of the implant.
- 32

- 1 Preferably the transverse members are arranged to
- 2 provide substantially even structural strength and
- 3 rigidity to the implant.
- 4
- 5 It may be desirable to secure the mesh in place once
- 6 it has been suitably located in the patient.
- 7
- 8 Preferably the mesh can be sutured to strong lateral
- 9 tissue.
- 10
- 11 Alternatively, the mesh may be glued in place using
- 12 a biocompatible glue.
- 13
- 14 This is advantageous, as it is fairly quick to apply
- 15 glue to the area around the surgical implant.
- 16
- 17 Preferably the mesh comprises at least one capsule
- 18 containing biocompatible glue for securing the
- 19 implant in place.
- 20
- 21 Preferably 4 capsules containing glue are provided
- 22 around the perimeter of the surgical implant.
- 23
- 24 Preferably the capsules comprise hollow thin walled
- 25 spheres of around 3 to 5 mm diameter including
- 26 gelatin.
- 27
- 28 Preferably the glue is a cyanoacrylate glue.
- 29
- 30 Conventionally, open procedures have been preferred
- 31 for the treatment of hernias with meshes, as
- 32 relatively broad access is required to the site of

1 the defect to suitably implant and secure a mesh by
2 sutures or such like.

3

4 However, it is desirable to treat hernias, as when
5 carrying out any surgery, with as little trauma to
6 the patient as possible. Thus, the use of minimally
7 invasive techniques has been suggested for the
8 treatment of hernias. However, such surgical
9 techniques have not been considered to be useful in
10 the treatment of uterovaginal prolapse with a mesh,
11 as it has not been considered practical to position
12 a mesh subcutaneously in the vaginal wall due to the
13 difficulty in gaining direct access to this area.

14

15 According to another aspect of the present
16 invention, there is provided a minimally invasive
17 method of treating uterovaginal prolapse, the method
18 comprising the steps;

19

20 making an incision in the vaginal wall close to
21 the opening of the vaginal cavity and,

22

23 making a subcutaneous cut, through the
24 incision, over and surrounding the area of the
25 prolapse, which cut is substantially parallel
26 to the vaginal wall; and

27

28 inserting a mesh according to the present
29 invention, through the incision, into the space
30 defined by the cut.

31

1 Thus, a mesh or the surgical implant such as that
2 according to the invention can be inserted through a
3 small incision (e.g. around 1cm to 2 cm in length)
4 at or in the region of the periphery or opening of
5 the vaginal cavity. An incision in this position is
6 easier for a surgeon to access than an incision
7 deeper in the vaginal cavity, yet the Applicant has
8 realised that it is also convenient to treat vaginal
9 prolapse by implanting a mesh in a surgical
10 procedure carried out entirely through such an
11 incision.

12

13 Preferably, the incision is at the anterior or
14 posterior extremity of the prolapse sac of the
15 vaginal cavity.

16

17 This is desirable as prolapse most often occurs in
18 the anterior or posterior vaginal wall, so
19 positioning the incision in such a location allows
20 the most convenient access to these parts of the
21 vaginal wall.

22

23 The provision of suitable handling characteristics
24 for the mesh is particularly advantageous when the
25 mesh is intended to be used in a conventional open
26 surgical procedure, as the surgeon needs to handle
27 the implant directly in order to place it in its
28 desired location.

29

30 However, the suitable placement particularly in the
31 treatment of uterovaginal prolapse, by minimally
32 invasive techniques require the mesh to be as

1 flexible as possible and therefore to have no
2 absorbable coating or encasement.

3

4 A flexible, less bulky mesh may be more easily
5 handled by tools that may be used to carry out the
6 procedure.

7

8 Tools that may be used to carry out this procedure
9 have a number of specific needs that need to be met
10 that are not presently met by conventional minimally
11 invasive surgical tools.

12

13 These specific needs can best be understood by
14 considering the steps of the surgical procedure of
15 the invention in turn.

16

17 The incision is made in the vaginal wall at the
18 opening of the vaginal cavity. This can be carried
19 out using a conventional implement such as a
20 scalpel. It is preferable that the incision is as
21 small as possible as this reduces trauma to the
22 patient.

23

24 A cut is then made in the vaginal wall over the
25 defect causing the prolapse or hernia. For example,
26 scissors or another specialised cutting tool can be
27 inserted through the incision and manipulated to
28 provide a cut over the defect. The cut is below the
29 surface of the skin and may provide a space between
30 an upper (or outer) layer and a lower (or inner)
31 layer of the vaginal wall, or between the skin and

1 the vaginal wall, in the region of the defect, into
2 which cavity the mesh can be inserted.

3

4 Next, the mesh is placed in the space defined by the
5 cut. It is preferred that the mesh of the invention
6 is supplied rolled up in order that it can be
7 inserted through a small incision and unfurled *in*
8 *situ*, i.e. in its intended position. Thus, it may
9 be possible for the surgeon to insert the mesh
10 through the incision by hand. However, this is
11 likely to result in the incision needing to be large
12 enough for the surgeon to insert a finger to
13 manipulate the mesh in the space. This may cause
14 unnecessary trauma to the patient and can be
15 difficult for a surgeon to carry out.

16

17 According to another aspect of the present
18 invention, there is provided a surgical tool for
19 delivering a mesh subcutaneously through an
20 incision, the tool being adapted to radially confine
21 the mesh during delivery and being operable to
22 release the mesh in its intended position.

23

24 Such a tool for placement of a mesh or the surgical
25 implant of the present invention can insert and
26 position the mesh or surgical implant in a
27 convenient and controlled manner through a small
28 incision. Furthermore, the incision through which
29 the mesh is inserted need only be as large as the
30 diameter of the tool, or the tool when carrying the
31 mesh, which can be significantly smaller than where

1 a surgeon's finger must be able to fit through the
2 incision.

3

4 Preferably the tool comprises a housing and
5 unfurling means the housing and unfurling means
6 insertable through an incision in the patient, the
7 housing and unfurling means adapted to accommodate a
8 rolled up mesh and separable to release the mesh the
9 unfurling means capable of unfurling the rolled up
10 mesh without any significant movement around the
11 area of the incision

12

13 Preferably, the tool comprises two or more parts,
14 the parts movable such that in a first position they
15 house the mesh or surgical implant and, in a second
16 position the mesh or surgical implant is released.
17 More preferably the tool comprises two semi-circular
18 channels, an inner channel having an external
19 diameter suitable for fitting inside an outer
20 channel.

21

22 The channels may be rotatable about a common axis
23 such that in a first position the open faces of the
24 channels face one another to form a closed housing
25 and in a second position the inner channel sits
26 inside the other channel to release the mesh.

27

28 Alternative the tool comprises a shaft and
29 releasable securing means, the shaft adapted such
30 that the mesh can be rolled around the shaft and
31 releasable securing means to secure the rolled mesh
32 in place.

1 In use, the tool is inserted through the incision
2 with the mesh rolled around the outside of the
3 shaft. Once the tool has been inserted, the mesh is
4 released by turning the shaft to unroll the mesh at
5 the same time as moving the shaft across the space
6 in which the mesh is being placed.

7
8 A needle may be used to secure the free, outer end
9 of the mesh whilst it is unfurled. The needle may
10 be inserted through the vaginal wall to pin the mesh
11 in place. Similarly, where the mesh is released
12 from within a housing, needles may be used to ease
13 the mesh out of the open housing.

14
15 In an alternate embodiment, the tool comprises two
16 or more arms, each of which is releasably attached
17 at one end to an edge of the surgical implant. The
18 arms may be movable from a first position in which
19 they radially confine the mesh to a second position
20 to unfurl the mesh in its intended position.

21
22 In one example, the arms are pivotally
23 interconnected such that they can be manipulated to
24 move the ends of the arms from the first position to
25 the second position.

26
27 In another example the arms may be arranged to
28 extend radially outward from a housing to move from
29 the first position to the second position. The
30 extendable arms may comprise wires arranged to be
31 extendable and retractable from and into the housing
32 by operation at an end of the housing.

1 In another example, the arms may be resilient or
2 sprung elements that can be released from the first
3 position and move into the second position to which
4 they are biased, i.e. to unfurl the mesh.

5

6 As can be appreciated, all of the above embodiments
7 of the tool are able to unfurl the mesh without any
8 significant movement around area of the incision.
9 For example, the pivot can be arranged to coincide
10 with the incision, the tool rolled around an arc
11 centred at the incision or the arms operated or
12 housing opened forward of the incision. Thus, the
13 incision can be small as no lateral movement is
14 required at the area of the incision.

15

16 Embodiments of the present invention will now be
17 described, by way of example only, with reference to
18 the accompanying drawings, in which:

19

20 Figure 1 is an illustration of a hernia;

21

22 Figure 2 is an illustration of the hernia of
23 figure 1 when intra-abdominal pressure is
24 raised;

25

26 Figure 3 is an illustration of the hernia of
27 figure 1 after repair in accordance with the
28 prior art;

29

30 Figure 4 is an illustration of the hernia of
31 figure 1 after an alternate repair in
32 accordance with the prior art;

1

2 Figure 5 is a schematic illustration of the
3 female human vaginal area;

4

5 Figure 6 is a cross-sectional view of the
6 female human vaginal area along the line A-A of
7 Figure 5;

8

9 Figures 7a and 7b illustrate surgical implants
10 according to the invention having a first
11 shape;

12

13 Figures 8a, 8b, 8c and 8d illustrate surgical
14 implants according to the invention having a
15 second shape;

16

17 Figures 9a, 9b 9c and 9d illustrate surgical
18 implants according to the invention having a
19 third shape;

20

21 Figure 10 illustrates a first surgical tool
22 according to the invention in cross-section;

23

24 Figure 11 illustrates a second surgical tool
25 according to the invention;

26

27 Figure 12 illustrates a third surgical tool
28 according to the invention; and

29

30 Figure 13 illustrates a fourth surgical tool
31 according to the invention.

32

1 Referring to Figures 1 and 2, a hernia, vaginal
2 prolapse or such like occurs when a fascial wall 1
3 ruptures, forming a defect 2, i.e. a weakening or,
4 in this case, parting of the fascial wall 1. An
5 organ 3, contained by the fascial wall 1 is then
6 able to protrude through the defect 2. Such
7 protrusion is illustrated in Figure 2 and occurs
8 particularly when pressure within the cavity defined
9 by the fascial wall 1 is raised. For example, in
10 the case of an inguinal hernia, when a patient
11 coughs, intra-abdominal pressure is raised and the
12 intestines may be pushed through the defect 2 in the
13 abdominal wall.

14

15 Whilst the organ 3 that may protrude through the
16 defect 2 is usually still contained by some other
17 membrane 4, the hernia, prolapse or such like is
18 inevitably painful and liable to infection or other
19 complications. An effective and desirable treatment
20 is therefore to close the defect 2 and contain the
21 organ 3 in its normal position.

22

23 Referring to Figure 3, hernias, vaginal prolapse and
24 such like are conventionally repaired by providing
25 sutures 5 across the defect 2 to join the tissues of
26 the fascial wall 1. In addition, it may be firstly
27 necessary to plicate (i.e. fold or reduce) the
28 membrane 4 as this may have stretched due to
29 distention of the organ 3. Plication of the
30 membrane 4 corrects the stretching and helps to
31 relieve pressure on the area of the defect 2 during
32 healing as the membrane 4 can act to contain the

1 organ 3 to some extent. Plication is generally
2 achieved by applying sutures 6 to the membrane 4.

3

4 Referring to Figure 4, it is also a known method of
5 treating hernias to provide, additionally or
6 alternatively to sutures, a mesh 7 across the defect
7 4. This allows for the defect 2 to be repaired
8 without the parted tissues of the fascial wall 1
9 necessarily being brought together and for the
10 defect to heal without the fascial wall 1 being
11 pinched or tensioned to correct the defect 2.

12

13 Figure 5 schematically illustrates (a sagittal view
14 of) the female human vaginal area. The vagina 8 is
15 illustrated with its anterior portion (front) at the
16 top of the diagram and the posterior portion (rear)
17 at the bottom of the diagram. The opening of the
18 urethra, or urethral meatus, 9 is at the forward or
19 anterior end of the vagina 8. The central portion
20 of the vagina 8 forms the vaginal cavity which
21 terminates at the cervix 10. Spaced from the
22 rearward or posterior end of the vagina 8 is the
23 anus 11. Four areas A to D of the vaginal wall 12
24 are outlined in figure 5. These areas A to D are
25 those areas of the vaginal wall 12 in which vaginal
26 prolapse often occurs.

27

28 Referring to figure 6, which is a cross sectional
29 view along the line A-A in figure 5, it can be more
30 clearly seen that the wall 12 of the vagina 8 is
31 bounded by the bladder 13 and urethra 14, the uterus
32 15, the small bowel 16 and rectum 17. The small

1 bowel 16 and rectum 17 are separated by the "Pouch
2 of Douglas" PoD.

3

4 Area A is the lower one third of the anterior
5 vaginal wall 12 (i.e. the one third nearest the
6 entrance to the vaginal cavity) adjacent the bladder
7 13 and urethra 14. Prolapse in this area is
8 referred to as anterior or, more specifically,
9 urethracocele prolapse. Area B is the upper two
10 thirds of the anterior vaginal wall 12. Prolapse in
11 this area is referred to as anterior or, more
12 specifically, cystocoele prolapse. The central area
13 of the vaginal wall 12 in which the cervix 10 is
14 located is adjacent the uterus 15 and prolapse in
15 this area is referred to as central, uterine or
16 vault prolapse. Area C is the upper one third of
17 the posterior vaginal wall 12. This area of the
18 vaginal wall 12 is adjacent the small bowel 16 and
19 prolapse in this area is referred to as posterior or
20 entremococele prolapse. Finally, area D is the lower
21 two thirds of the posterior vaginal wall and is
22 adjacent the rectum 17. Prolapse in this area is
23 generally referred to as posterior or rectocoele
24 prolapse.

25

26 Conventionally, any of the above types of hernia
27 have been treated by providing sutures in the area
28 of the prolapse. For example, the extent of the
29 defect causing the prolapse is first identified by
30 the surgeon. Lateral sutures, i.e. sutures from one
31 side to the other of the vaginal wall 12 as seen in
32 figure 5 or right to left rather than anterior to

1 posterior, are provided across the area of the
2 defect. This joins the parted tissues of the
3 vaginal wall and repairs the defect. The organ
4 protruding through the vaginal wall is therefore
5 contained. Disadvantages of this technique include
6 anatomical distortion of the vagina due to
7 tensioning of the wall by the sutures to repair the
8 defect.

9

10 A surgical implant for use in the repair of vaginal
11 prolapse in accordance with an embodiment of the
12 present invention comprises a mesh 20. The mesh is
13 comprised of strands 22. The strands being less
14 than 600 µm and approximately 150 to 600 µm in
15 diameter. The strands are arranged such that they
16 form a regular network and are spaced apart from
17 each other such that for a diamond net a space of
18 between 2mm to 5mm exists between the points where
19 the strands of the mesh interact with each other
20 (a). In a hexagonal net arrangement the space is
21 between 2mm to 5mm between opposite diagonal points
22 where the strands of the mesh interact (b).

23

24 It is preferable to space the strands as far as part
25 as possible to allow blood to pass through the
26 implant and reduce the mass of the implant, while
27 providing the mesh with sufficient tensile strength
28 and elasticity to be effective. It can therefore be
29 appreciated that considerable variability in the
30 maximum spacing between the strands can be achieved
31 depending of the material from with the strands are

1 comprised and the net pattern in which the strands
2 are arranged.

3

4 In the embodiment shown in figure 7a the strands are
5 arranged in a diamond net pattern 24, however any
6 pattern which provides suitable tensile strength and
7 elasticity may be used.

8

9 For example a hexagonal net pattern may be used as
10 shown in figure 7b.

11

12 Ideally in order to reduce the overall mass of the
13 implant the strands 22 should have as narrow a
14 diameter as possible while still providing the mesh
15 20 with suitable tensile strength and elasticity.

16

17 The strands 22 of the mesh 20 are comprised of at
18 least two filaments 26 arranged to interact such
19 that pores 28 are formed between the filaments 26.

20

21 The pores 28 formed between the filaments 26 are
22 around 50 to 200 μm , such a spacing allowing
23 fibroblast through growth to occur. This fibroblast
24 through growth secures the implant 20 in place
25 within the body. Additionally and importantly the
26 suitably sized pores allow the implant 20 to act as
27 a scaffold to encourage the lay down of new tissue.
28 The lay down of new tissue promotes the healing of
29 the hernia.

30

31 The filaments 26 may be formed from any
32 biocompatible material. In this embodiment the

1 filaments 26 are formed from polyester, wherein each
2 polyester filament 26 is around 0.09 mm in diameter.

3

4 In the embodiment shown the filaments 26 of the
5 strands 24 are knitted together using warp knit to
6 reduce the possibility of fraying of the filaments
7 26 and strands 24.

8

9 Alternative suitable materials of which the
10 filaments may be formed include polypropylene.

11

12 Suitable materials from which the mesh can be made:
13 provide sufficient tensile strength to support a
14 fascial wall during repair of a defect in the
15 fascial wall causing a hernia; are sufficiently
16 inert to avoid foreign body reactions when retained
17 in the human body for long periods of time; can be
18 easily sterilised to prevent the introduction of
19 infection when the mesh is implanted in the human
20 body; and have suitably easy handling
21 characteristics for placement in the desired
22 location in the body.

23

24 The fine warp knit of the filaments 26 provides a
25 surgical implant which is flexible in handing, which
26 can be easily cut into different shapes and
27 dimensions. As the strands 24 are formed using warp
28 knit the possibility of fraying of the edge of the
29 surgical implant 20 following production or cutting
30 of the surgical implant 20 is reduced.

31

1 Other methods of reducing fraying of the filaments
2 24, not arranged to form the strands using warp
3 knit, following cutting or production of the implant
4 are heat treatment, laser treatment or the like to
5 seal the edges of the surgical implant.

6

7 The mesh 20 may be supplied in any shape or size and
8 cut to the appropriate dimensions as required by the
9 surgeon.

10

11 It can be appreciated that cutting of the mesh will
12 produce an unfinished edge 30. Due to the sparse
13 nature of the strands that form the mesh and their
14 narrow diameter this unfinished edge does not suffer
15 from the same problems as edges of meshes of the
16 prior art.

17

18 In other words the edge produced is not rough and
19 jagged such that it increases the likelihood of
20 extrusion of the edge of the mesh *in situ* or the
21 chance of infection.

22

23 As discussed an advantage of the mesh of the present
24 invention is that it allows the production of a mesh
25 suitable for use in hernia repair which allows
26 substantially less foreign material to be left into
27 the body.

28

29 However, the mesh being flexible and insubstantial
30 is less suitable for allowing easy handling of the
31 mesh directly by a surgeon. Referring to figure 8a

1 and 8b the mesh described above may be treatable
2 using an absorbable coating 32.

3

4 The absorbable coating 32 comprises a layer of
5 absorbable material having a thickness greater than
6 that of the strands 22 of the mesh 20. For example,
7 the thickness of the layer of absorbable material
8 may be around 1 to 2 mm. The strands 22 of the mesh
9 20 may be entirely embedded in the absorbable
10 coating 32 such that the outer surface of the mesh
11 20 is covered entirely of the absorbable coating 32.

12

13 In effect the entire surgical implant is encased in
14 the absorbable coating as shown in figure 8b.

15

16 Thus, the surgical implant has no gaps or holes on
17 its surface. This has the advantage of reducing the
18 likelihood of bacteria becoming lodged on the
19 strands 22 of the mesh 20 before implantation of the
20 mesh 20. Furthermore, the absorbable coating 32
21 makes the mesh 20 more substantial and less flexible
22 such that it is more easily handled by a surgeon.
23 This is particularly useful when it is desired to
24 place the mesh in a desired location in a
25 conventional, open surgical procedure.

26

27 In an alternative embodiment shown in figure 8a the
28 absorbable coating 32 comprises a layer of
29 absorbable material applied to one face 34 of the
30 mesh 20, such that the mesh has a first face 34 on
31 which the absorbable material has been applied and a
32 second face 36 on which the absorbable material has

1 not been applied such that the first and second
2 faces 34 and 36 each have different characteristics.
3

4 It can also be envisaged that the surgical implant
5 is provided with improved surgical handling
6 qualities by a range of other methods. Such methods
7 including, the releasable attachment of the mesh 20
8 to a backing strip 40. This embodiment is shown in
9 figure 8c.

10

11 The backing strip may be formed from plastics
12 material and is adhered to the surgical implant
13 using releasable adhesive.

14

15 In a similar fashion to the absorbable coating the
16 backing strip 40 causes the mesh 20 to be more
17 substantial and less flexible such that it is more
18 easily handled by a surgeon. Following the suitable
19 placement of the mesh 20 the backing strip 40 can be
20 removed from the mesh 20, the mesh 20 being retained
21 in the body and the backing material 40 being
22 removed by the surgeon. Application of the backing
23 strip 40 to the mesh 20 means the mesh 20 benefits
24 from reduced mass but that the mesh 20 and backing
25 strip 40 together give characteristics required for
26 surgical handling.

27

28 In a further embodiment the filaments of the mesh
29 may be comprised from bicomponent microfibres 50 or
30 composite polymers 60. These technologies provide
31 the implant with dual phase technology.

32

1 As shown in figure 8d the bicomponent microfibres 50
2 comprise a core 52 (cutaway section shows core
3 region) and surface material 54. The surface
4 material 54 is designed such that it is absorbed by
5 the body in a matter of hours, while the core
6 material 52 remains in the body for a longer period
7 to enable tissue ingrowth.

8
9 Suitable bicomponent microfibres 50 include a
10 polypropelene non absorable portion and a polylactic
11 acid absorbable portion.

12
13 The surface material 54 is present during the
14 surgical procedure when the mesh 20 is being
15 inserted and located in the patient, and provides
16 the mesh with characteristics desirable for surgical
17 handling. Following a period of insertion in the
18 body, typically a few hours, the surface material 54
19 is absorbed into the body leaving only the core
20 material 52 of the filaments 26 in the body. The
21 core material of the filament having reduced foreign
22 mass in comparison to meshes of the prior art or the
23 mesh 20 when it also includes the surface material
24 54.

25
26 As shown in figure 8e the mesh of the surgical
27 implant may be formed composite polymers 60. As
28 described for the bicomponent microfibres 50,
29 composite polymers 60 provide the surgical implant
30 with dual phase technology. A first face 62 of the
31 mesh 20 thus having particular characteristics such
32 as flexibility and elasticity, while a second face

1 64 of the mesh 20 provides the mesh 20 with
2 characteristics which improved the surgical handling
3 of the mesh 20 such as strength and robustness.
4 The cutting of the mesh described causes an
5 unfinished edge of the mesh to be produced. This
6 unfinished mesh not being as likely to cause the
7 same problems as the rough and jagged edges of the
8 implants of the prior art, due to the fewer strands,
9 smaller diameter filaments and treatment of the mesh
10 with absorbable coating which protects the tissue
11 from the mesh during the surgical procedure when
12 damage is most likely to occur.
13
14 Referring to 9a, a further embodiment of the mesh
15 may comprise strands as discussed and more
16 specifically, perimeter strands. Typically the mesh
17 is circular or the like in shape and thus this
18 perimeter strand can be generally referred to as a
19 circumferential strand 70.
20
21 In the example shown in figure 9a one strand runs
22 around the circumference of the oval shape of the
23 mesh 20. In another embodiment, several
24 circumferential strands 70 may be present, each
25 circumferential strand 70 may extend over one side
26 of the oval mesh 20, i.e. around half the
27 circumference of the mesh.
28
29 As shown in figure 9b the circumferential strands 70
30 are arranged concentrically and each extends around
31 the mesh 20 at a different radial location.
32

1 An outer circumferential strand 70 extending around
2 the perimeter of the mesh 20, and further
3 circumferential strands 72 and 74 are arranged
4 inwardly of the outer circumferential strand forming
5 a perimeter spaced by a distance (a). The distance
6 a between adjacent circumferential members 70, 72
7 and 74, can vary and in this example is 20 mm.
8

9 Transverse strands 76 extend from the centre of the
10 oval mesh 20 to points on the perimeter of the mesh
11 78. In this example, four transverse strands 76 are
12 provided across the diameter of the mesh 20,
13 dividing the mesh 18 into eight angularly equal
14 portions.

15
16 The mesh 20 of this embodiment may be formed from
17 materials as previously described. Depending on the
18 material chosen the mesh may be woven, knitted or
19 extruded as one piece, or individual or groups of
20 strands can be extruded separately and joined to one
21 another.

22
23 Such a construction as described above provides a
24 mesh 20 with sufficient tensile strength to repair
25 defects causing vaginal prolapse whilst having
26 minimal bulk. Similarly, such a construction
27 provides a suitably flexible yet resilient mesh for
28 handling using the surgical tools described below.
29 Referring to figures 9c and 9d, meshes 80, 82 of in
30 the shape of the outline having angled sides
31 respectively, rather than oval, are illustrated.
32

- 1 These meshes have a similar structure to that
2 described with reference to figure 9a and b.
3 However, the mesh has a perimeter member 80 having
4 angled sides. Further it may have transverse
5 members arranged only to extend towards the
6 perimeter of the mesh, rather than all being across
7 the diameter of the mesh. This provides a more
8 uniform structure. More specifically, referring to
9 figure 9d the mesh has a transverse member 84
10 extending along its axis of symmetry, a transverse
11 member 86 bisecting the axis of symmetry, and four
12 further transverse members 88 extending from the
13 axis of symmetry to the perimeter of the mesh 90.
- 14
- 15 In addition to the pores provided by the combination
16 of filaments 26 which form the strands 22, pores can
17 be provided by rings of polypropylene positioned at
18 the intersection of the circumferential and
19 transverse members.
- 20
- 21 Alternatively the pores may be formed by the spacing
22 of the transverse members, such that pores of a size
23 50-200 μm suitable for enabling tissue ingrowth exist
24 between the transverse members.
- 25
- 26 To secure the mesh to a suitable location in the
27 body a number of methods can be used. The tackiness
28 of the absorbable coating may hold the mesh suitably
29 until it is secured by tissue ingrowth.
- 30
- 31 Alternatively the surgical implant can have capsules
32 100(not shown) of biocompatible glue for securing

1 the mesh 20 in place. In this example, six capsules
2 100 comprising spheres having a diameter of 4 mm and
3 made from a rapidly absorbable material are provided
4 around the perimeter of the mesh 20. On placement
5 in the body, the capsules 100 dissolve and release a
6 biocompatible glue contained within to secure the
7 mesh 20 in place.

8

9 Referring to figure 10, a tool 200 for inserting one
10 of the meshes described (usually without an
11 absorbable coating 32) comprises two channels 202,
12 204. The channels 202, 204 are semi-circular in
13 cross-section and the channel 202 has a diameter
14 slightly smaller than the diameter of channel 204.
15 The channels are interconnected such that the
16 channel 202 can be rotated inside the channel 204.
17 In use, the mesh 20 is rolled up and placed in the
18 space formed by the channels 202, 204 in a first
19 position in which the open sides of the channels
20 face one another to form a housing or tube. After
21 insertion into the desired location, channel 204 is
22 rotated inside the channel 202 to release the mesh
23 20.

24

25 Referring to figure 11, an alternative tool 210 for
26 inserting one of the meshes described comprises an
27 elongate housing 212 around which the mesh is rolled
28 and secured. The tool 210 has means for trapping an
29 edge of the mesh 20 to secure it on the housing of
30 the tool 212, such as a groove 214. In use, once
31 the mesh 20 has been rolled around the housing of
32 the tool 210 it may be secured by a removable clip

1 or other such retaining means (not shown). After
2 insertion of the tool 210 into the desired location,
3 the mesh 20 is released and the tool 210 is rotated
4 to unfurl the mesh 20.

5

6 Referring to figure 12, another alternative tool 220
7 for inserting one of the meshes described above in
8 the body comprises two arms 222 pivotally
9 interconnected by a pivot 224. One end of each arm
10 226 has means for being releasably attached to the
11 mesh 20. The other end of each arm 228 is operable
12 to move the ends that may be attached to the mesh 20
13 toward or away from one another by rotation around
14 the pivot 224. When the ends of the arms 226,228 to
15 which the mesh 20 can be attached are moved to a
16 position in which they are close to one another, the
17 tool 220 is substantially elongate. Furthermore,
18 the mesh 20 is radially confined by the arms. Once
19 the mesh 20 has been inserted into position, the
20 arms 226,228 can be manipulated to move the ends to
21 which the mesh 20 can be attached apart to unfurl
22 the mesh 20 in its intended position.

23

24 Referring to figure 13, another tool 230 for
25 inserting one of the meshes described above in its
26 desired location comprises an elongate housing 232
27 having a number of pairs of holes 234 spaced along
28 its length (in this example three pairs) at the
29 distal end of the tool 230. The housing 232 is
30 hollow and contains a number (in this case three) of
31 pairs of wires 236, made from polypropylene for
32 example, which extend along the length of the

1 housing 232 and out through the pairs of holes 234.
2 The wires 236 also protrude from the proximal end of
3 the housing such that they can be pushed and pulled
4 in and out of the housing 232. The ends of the
5 wires 236 that protrude from the holes 234 have
6 means for releasably attaching to points near the
7 perimeter of the mesh 20.

8

9 In use, the wires 236 are attached to the mesh 20
10 and retracted by pulling them back through the
11 housing 30 such that the mesh 20 is radially
12 confined close to the housing 232. Once the tool
13 230 has been inserted into the intended position,
14 the wires 236 are pushed into the housing 232 and
15 consequently out through the holes 234 to urge the
16 mesh 20 away from the housing 232. Thus, the mesh
17 20 can be unfurled in its desired location in the
18 body.

19

20 Referring once again to figure 5 in order to repair
21 a urethracocele prolapse i.e. a defect in the area A
22 of figure 5, the surgeon first locates the defect by
23 examining the patient in the conventional manner.
24 The extent of the defect can then be ascertained
25 and, if necessary, a suitable template used to
26 estimate the shape and dimensions of a preferred
27 surgical implant to repair the defect. A suitably
28 shaped surgical implant can then be selected.

29

30 The meshes described above are, in this example,
31 supplied in a single size. After examination of the
32 patient and estimation of the desired dimensions of

1 the preferred mesh, the surgeon cuts the mesh to the
2 preferred size.

3

4 Where the mesh comprises a circumferential member 70
5 the cut made in the mesh is through the transverse
6 members 76 just outward of the circumferential
7 member 70 corresponding most closely with the
8 preferred size of mesh. Thus, regardless of the
9 size to which the mesh is to be cut, a
10 circumferential member 70 defines the perimeter of
11 the mesh, and the perimeter of the mesh is
12 substantially smooth. This desirably reduces the
13 likelihood of infection or edge erosion once the
14 mesh is inserted in the body.

15

16 The surgeon then attaches the mesh to or inserts the
17 mesh with one of the insertion tools described
herein. For example, the mesh is rolled up and
18 placed within the insertion tool 200 illustrated in
19 figure 10, wrapped around the insertion tool 210
20 illustrated in figure 11, attached to the ends of
21 the arms 222 of the insertion tool 220 illustrated
22 in figure 12 or attached to the ends of the wires
23 236 of the insertion tool 230 illustrated in figure
24 13.

26

27 An incision 9 is then made in the vaginal wall 12 at
28 the forward most portion of the vaginal wall 12
29 adjacent the opening of the vaginal cavity. A
30 cutting implement (not illustrated), such as
31 scissors or a specialised cutting tool, is/are then
32 inserted through the incision 9 into the area A,

1 i.e. the lower portion of the anterior vaginal wall
2 12. Using the cutting implement, a cut is made in
3 the area A parallel with the surface of the vaginal
4 wall 12. In other words, a space is opened up in
5 the vaginal wall 12 over the area of the defect in
6 the vaginal wall 12. The cutting implement is then
7 withdrawn and the mesh 20 is inserted in the space
8 defined by the cut.

9

10 Where the insertion tool 200 illustrated in figure
11 10 is used, the tool 200 is inserted into the area A
12 and the channel 202 rotated to a position within the
13 channel 204 to release the mesh 20. The insertion
14 tool 200 can then be retracted and the mesh unfurls
15 due to its inherent resilience or flat memory.
16 Should it be required to help the mesh 20 to unfurl,
17 or slightly re-position the mesh 20 defect 2, an
18 elongate tool (not shown) may be inserted through
19 the incision 9 or needles may be introduced directly
20 through the vaginal wall 12 to manipulate the mesh
21 20. This procedure can be viewed laproscopically
22 through the incision 9 if desired.

23

24 Where the insertion tool 210 illustrated in figure
25 11 is used, it is desirable for the insertion tool
26 210 to be inserted to one side of the space defined
27 by the cut. The mesh 20 is then released and a
28 needle inserted through the vaginal wall to hold the
29 released edge of the mesh 20 in position. The tool
30 210 is then rolled across the space defined by the
31 cut in an arc having a centre of rotation around the
32 incision 9. Thus, the mesh 20 is unfurled, but no

1 significant movement is required around the incision

2 9.

3

4 Where the insertion tool 220 illustrated in figure
5 12 is used, the insertion tool 220 is simply
6 inserted through the incision 9 and opened to expand
7 the mesh 20 into its desired location. The mesh 20
8 is released from the insertion tool 220 which can
9 then be closed and withdrawn through the incision 9.

10

11 Finally, where the insertion tool 250 illustrated in
12 Figure 13 is used, the mesh 20 is retracted by
13 withdrawing the wires 236 through their holes 234
14 and the mesh is inserted through the incision 9.
15 Once the insertion tool 230 has been inserted into
16 its desired location, the wires 236 are urged
17 forward and out through the holes 234 to expand the
18 mesh in its intended position. The wires 236 can
19 then be released from the mesh 20, withdrawn into
20 the housing 232 and the tool 230 withdrawn through
21 the incision 9.

22

23 Once the mesh 20 is in place, the incision may be
24 closed.

25

26 However, it can be desirable to secure the 20 in
27 place, rather than rely on the mesh 20 remaining in
28 its desired location of its own accord. In one
29 example, sutures are therefore be placed either
30 laproscopically through the incision 9 or directly
31 through the vaginal wall 12 to hold the mesh 20 in
32 place. In another example, glue capsules provided

1 on the mesh 20 dissolve to secure the mesh 20 to the
2 tissue surrounding the space defined by the cut, or
3 such capsules may be punctured by needles inserted
4 directly through the vaginal wall 12.

5

6 The surgical implant described herein is
7 advantageous over the meshes of the prior art in
8 several ways.

9

10 In particular the mesh of the present invention
11 includes smoother edges, the polyester material of
12 the present invention being softer than
13 polypropylene. Further, the filaments of the
14 present invention are narrower in diameter enabling
15 them to be more pliable than the strands of the
16 meshes of the prior art. This causes the edge or
17 edges of the mesh of the present invention to have
18 fewer jagged edges and thus be smoother than the
19 edges of meshes of the prior art.

20

21 In addition encasement of the mesh in an absorbable
22 coating further protects the tissue both during
23 placement and for a period of time after placement
24 of the surgical implant.

25

26 Dual Phase Technology™ such as encasement in an
27 absorbable coating or as otherwise discussed herein
28 provides the implant with good handling
29 characteristics, further it enables the implant to
30 be more easily cut. As described above an
31 absorbable coating may protect the tissues around
32 where the implant is to be located both during

1 placement and for a period of time following
2 placement of the implant in the tissue.

3

4 Dual Phase Technology™ may also provide the implant
5 with memory. This memory may allow the implant to
6 be more easily placed flat on the tissue. Further
7 the dual phase technology such as an absorbable
8 coating may provide the implant with mild adhesive
9 properties or tackiness which would aid both the
10 locating and securing of the implant in the tissue.

11

12 The surgical implant described herein thus allows
13 tension free repair of hernias, particular vaginal
14 prolapse, with minimum pain. This allows the
15 procedure to be performed under local anaesthetic in
16 an out patient or office setting.

17

18 Whilst the above embodiments of the invention have
19 been described with reference to vaginal prolapse,
20 the mesh and surgical tools may equally be used to
21 repair any bodily hernia. Furthermore, whilst the
22 above procedure has been described in relation to a
23 urethrocoele prolapse, prolapse in other parts of
24 the vaginal wall 12 can be treated through incisions
25 elsewhere in the vaginal wall, or other bodily
26 hernias through suitable incisions in the
27 appropriate tissue.

1 **Claims**

2

3 1. A surgical implant suitable for treatment of
4 hernias, the implant comprising a mesh comprising
5 strands having a maximum residual mass density of
6 50g/m².

7

8 2. An implant as claimed in claim 1 wherein the
9 mesh has a maximum residual mass density of less
10 than 30g/m².

11

12 3. A surgical implant as claimed in claims 1 or 2
13 wherein the mesh comprises strands and includes
14 major spaces and pores, the spaces existing between
15 the strands and pores formed within the strands.

16

17 4. An implant as claimed in any preceding claim
18 wherein strands are formed from at least two
19 filaments.

20

21 5. A surgical implant as claimed in any preceding
22 claim wherein the strands are spaced apart to form
23 major spaces of 1 to 10 mm.

24

25 6. A surgical implant as claimed in any preceding
26 claim wherein the strands have a diameter of less
27 than 600µm.

28

29 7. A surgical implant as claimed in any preceding
30 claim wherein the strands are arranged to form a
31 warp knit diamond or hexagonal net mesh.

32

1 8. A surgical implant as claimed in any preceding
2 claim wherein the strands are arranged to form a net
3 mesh which has isotropic or near isotropic tensile
4 strength and elasticity.

5

6 9. A surgical implant as claimed in any preceding
7 claim wherein the filaments have a diameter of
8 between 0.02 to 0.15 mm.

9

10 10. A surgical implant as claimed in any preceding
11 claim wherein the filament of the mesh is of a
12 diameter 0.05 to 0.1 mm.

13

14 11. A surgical implant as claimed in any preceding
15 claim wherein a monofilament or at least two
16 filaments are interwoven/knitted such that the
17 strands of the mesh comprise pores.

18

19 12. A surgical implant as claimed in any preceding
20 claim wherein the pores in the strands are of
21 between 50 to 200 μm in diameter.

22

23 13. A surgical implant as claimed in any preceding
24 claim further comprising rings of material
25 comprising pores of between 50 to 200 μm adhered to
26 on the strands of the mesh to provide pores.

27

28 14. A surgical implant as claimed in any preceding
29 claim wherein the pores in the strands are of
30 between 50 to 75 μm in diameter.

31

1 15. A surgical implant as claimed in any preceding
2 claim wherein the filaments of the mesh comprise a
3 plastics material.

4

5 16. A surgical implant as claimed in any preceding
6 claim wherein the filaments of the mesh comprise a
7 synthetic material.

8

9 17. A surgical implant as claimed in any preceding
10 claim wherein the filaments of the mesh comprise an
11 absorbable material.

12

13 18. A surgical implant as claimed in any of claims
14 1 to 16 wherein the filaments of the mesh comprise
15 polypropylene.

16

17 19. A surgical implant as claimed in any of claims
18 1 to 16 wherein the filaments of the mesh comprise
19 polyester.

20

21 20. A surgical implant as claimed in any preceding
22 claim wherein the implant has an absorbable coating
23 which degrades within 48 hours.

24

25 21. A surgical implant as claimed in claim 20
26 wherein the absorbable coating encapsulates the mesh
27 of the surgical implant.

28

29 22. A surgical implant as claimed in claim 20
30 wherein the absorbable coating is applied to at
31 least one face of the mesh.

32

- 1 23. A surgical implant as claimed in claims 20 to
- 2 22 wherein the absorbable coating comprises any
- 3 suitable soluble and biocompatible material.
- 4
- 5 24. A surgical implant as claimed in claims 20 to
- 6 23 wherein the absorbable coating is a soluble
- 7 hydrogel such as gelatin.
- 8
- 9 25. A surgical implant as claimed in claims 20 to
- 10 23 wherein the absorbable coating is a starch or
- 11 cellulose based gel.
- 12
- 13 26. A surgical implant as claimed in claims 20 to
- 14 23 wherein the absorbable coating is an alginate.
- 15
- 16 27. A surgical implant as claimed in claims 20 to
- 17 26 wherein the coating is of a thickness greater
- 18 than that of the mesh.
- 19
- 20 28. A surgical implant as claimed in any preceding
- 21 claim comprising a backing strip wherein the backing
- 22 strip is releasably attachable to the mesh.
- 23
- 24 29. A surgical implant as claimed in claim 28
- 25 wherein the backing strip is formed from plastics.
- 26
- 27 30. A surgical implant as claimed in claims 28 or
- 28 29 wherein the surgical implant is releasably
- 29 attachable to the backing strip by adhesive.
- 30

1 31. A surgical implant as claimed in any preceding
2 claim wherein the strands of the mesh are comprised
3 of bicomponent microfibres.

4

5 32. A surgical implant as claimed in claim 31
6 wherein the bicomponent microfibres comprise a core
7 and surface material.

8

9 33. A surgical implant as claimed in claim 32
10 wherein the surface material is capable of being
11 absorbed by the body in a period of less than 48
12 hours.

13

14 34. A surgical implant as claimed in claims 32 or
15 33 wherein the core material is capable of remaining
16 in the body for a period of time sufficient to
17 enable tissue ingrowth.

18

19 35. A surgical implant as claimed in claim 32
20 wherein the surface material is polylactic acid and
21 the core material is polypropylene.

22

23 36. A surgical implant as claimed in any preceding
24 claim wherein the surgical implant comprises
25 material that has memory.

26

27 37. A surgical implant as claimed in claim 36
28 wherein the surgical implant has memory which urges
29 the surgical implant to adopt a flat conformation.

30

1 38. A surgical implant as claimed in any preceding
2 claim wherein the implant has a generally curved
3 perimeter.

4
5 39. A surgical implant as claimed in any preceding
6 claim wherein the surgical implant is of width
7 between 1 cm to 10 cm and of length between 1 cm to
8 10 cm.

9
10 40. A surgical implant as claimed in any preceding
11 claim wherein the implant is any one of round,
12 circular, oval, ovoid elliptical or truncated
13 elliptical or some similar shape.

14
15 41. A surgical implant as claimed in any preceding
16 claim wherein the mesh can be cut to any desired
17 shape.

18
19 42. A surgical implant as claimed in any preceding
20 claim wherein the mesh has at least one
21 circumferential member which extends, in use, along
22 at least part of the perimeter of the implant to
23 provide a substantially smooth edge.

24
25 43. A surgical implant as claimed in claim 42
26 wherein at least part of the perimeter of the
27 implant is defined by the circumferential member.

28
29 44. A surgical implant as claimed in claims 42 or
30 43 wherein at least 50% of the perimeter of the
31 implant is defined by the circumferential member(s).

32

1 45. A surgical implant as claimed in claims 42 to
2 44 wherein at least 80% of the perimeter of the
3 implant is defined by the circumferential member(s).

4

5 46. A surgical implant as claimed in claims 42 to
6 45 wherein 100% of the perimeter of the implant is
7 defined by the circumferential member(s).

8

9 47. A surgical implant as claimed in claims 42 to
10 46 wherein the perimeter of the mesh is defined, in
11 use, by one circumferential member.

12

13 48. A surgical implant as claimed in claims 42 to
14 47 wherein the mesh has a plurality of
15 circumferential members arranged at different radial
16 locations.

17

18 49. A surgical implant as claimed in claim 48
19 wherein the circumferential members are arranged to
20 join with one another in order to form an integral
21 mesh.

22

23 50. A surgical implant as claimed in claim 42 to 49
24 wherein the mesh comprises transverse members which
25 extend across the circumferential members joining
26 the circumferential members.

27

28 51. A surgical implant as claimed in claim 50
29 wherein the transverse members extend radially from
30 a central point to the perimeter of the implant.

31

- 1 52. A surgical implant as claimed in claim 50 or 51
2 wherein the transverse members extend toward the
3 perimeter of the implant.
- 4
- 5 53. A surgical implant as claimed in any preceding
6 claim wherein the mesh can be glued in place using a
7 biocompatible glue.
- 8
- 9 54. A surgical implant as claimed in any preceding
10 claim comprising at least one capsule containing
11 biocompatable glue for securing the implant in
12 place.
- 13
- 14 55. A surgical implant as claimed in claim 54
15 comprising four capsules containing glue provided
16 around the perimeter of the surgical implant.
- 17
- 18 56. A surgical implant as claimed in claims 54 or
19 55 wherein the capsules comprise hollow thin walled
20 spheres of around 3 to 5 mm diameter including
21 gelatin.
- 22
- 23 57. A surgical implant as claimed in claims 54 to
24 56 wherein the glue is a cyanoacrylate glue.
- 25
- 26 58. A minimally invasive method of treating
27 uterovaginal prolapse, the method comprising the
28 steps;
- 29
- 30 making a 1-2cm length incision in the vaginal
31 wall close to the opening of the vaginal cavity
32 and,

1 making a subcutaneous cut, through the
2 incision, over and surrounding the area of the
3 prolapse, which cut is substantially parallel
4 to the vaginal wall; and

5
6 inserting a mesh according to the present
7 invention, through the incision, into the space
8 defined by the cut.

9
10 59. A method of treating uterovaginal prolapse as
11 claimed in claim 58 wherein the incision is at the
12 posterior extremity of the prolapse sac of the
13 vaginal cavity.

14
15 60. A method of treating uterovaginal prolapse as
16 claimed in claim 58 wherein the incision is at the
17 anterior extremity of the prolapse sac of the
18 vaginal cavity.

19
20 61. A surgical tool for delivering a surgical
21 implant as described in claims 1 to 57
22 subcutaneously through an incision, the tool being
23 adapted to radially confine the surgical implant
24 during delivery and being operable to release the
25 mesh in its intended position.

26
27 62. A surgical tool as claimed in claim 61
28 comprising a housing and unfurling means the housing
29 and unfurling means insertable through an incision
30 in the patient, the housing and unfurling means
31 adapted to accommodate a rolled up mesh and
32 separable to release the mesh, the unfurling means

1 capable of unfurling the rolled up mesh without any
2 significant movement around the area of the incision
3

4 63. A surgical tool as claimed in claim 61 or 62
5 comprising two or more parts, the parts movable such
6 that in a first position they house the mesh or
7 surgical implant and, in a second position the mesh
8 or surgical implant is released. More preferably
9 the tool comprises two semi-circular channels, an
10 inner channel having an external diameter suitable
11 for fitting inside an outer channel.

12
13 64. Use of an implant as claimed in any of claims 1
14 to 57 in the treatment of inguinal hernia,
15 incisional hernia or uterovaginal prolapse.

1 / 10

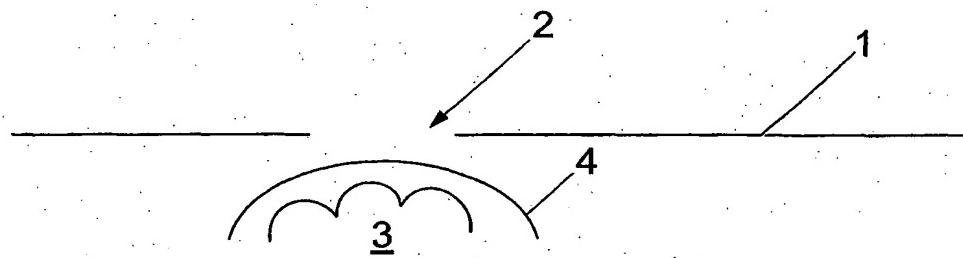


Fig. 1

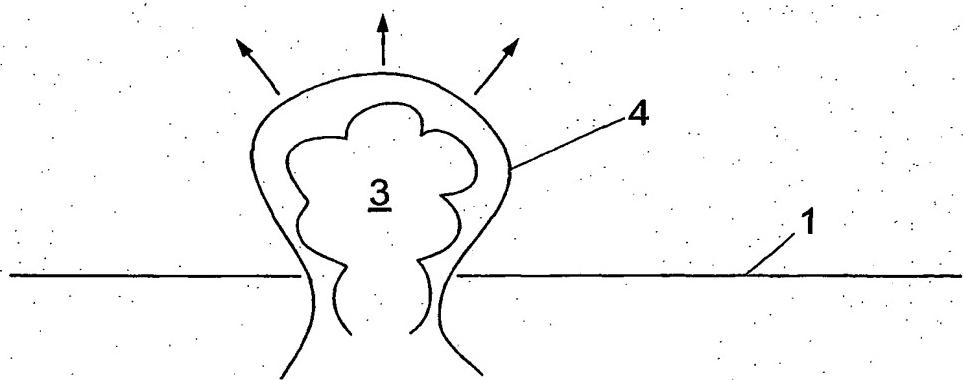


Fig. 2

2 / 10

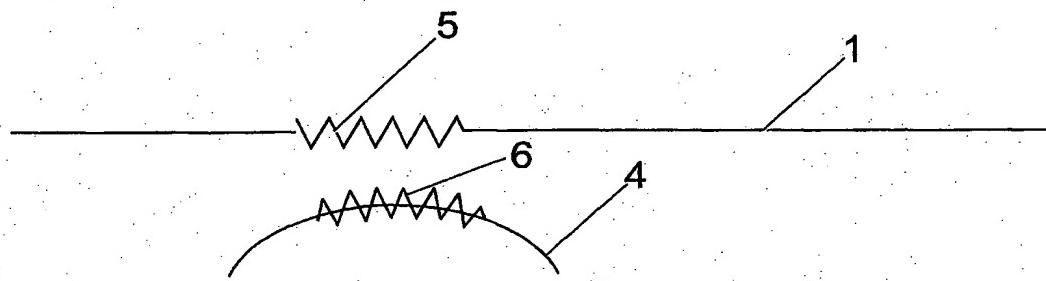


Fig. 3

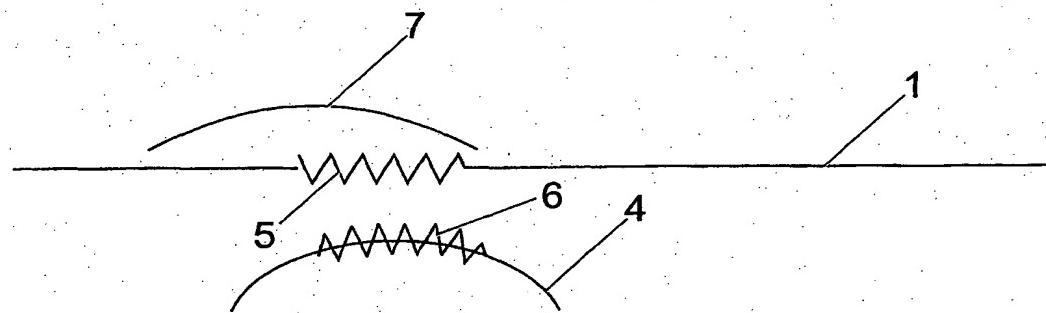
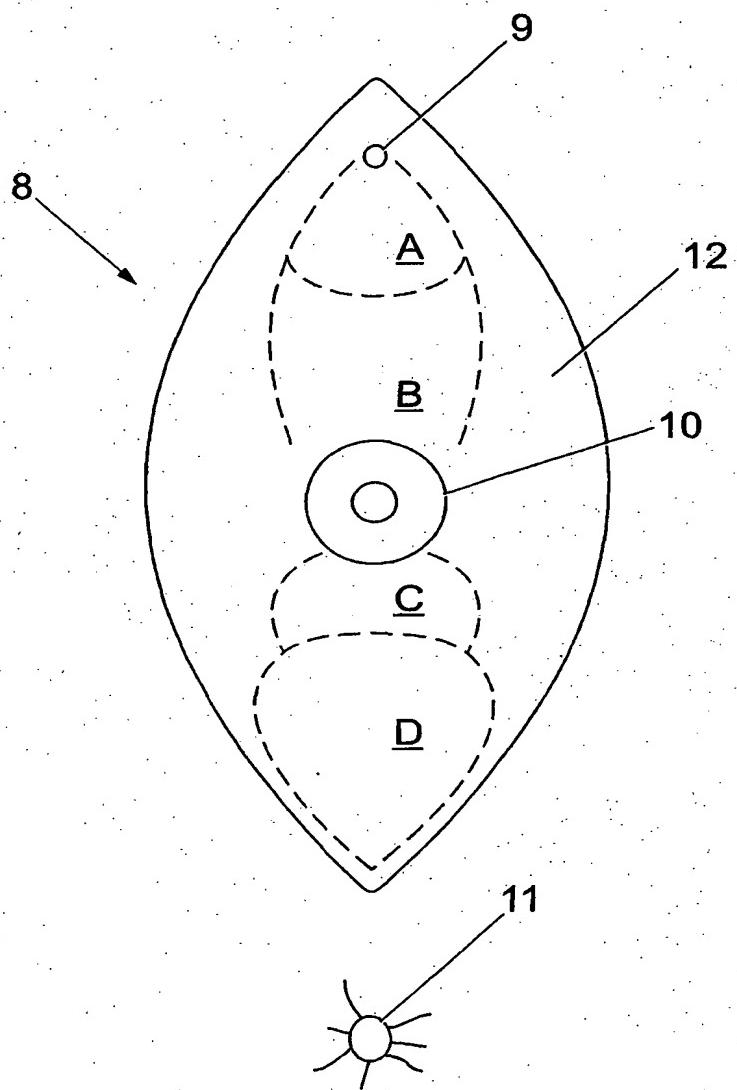


Fig. 4

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SECTION A-A

Fig. 5

4 / 10

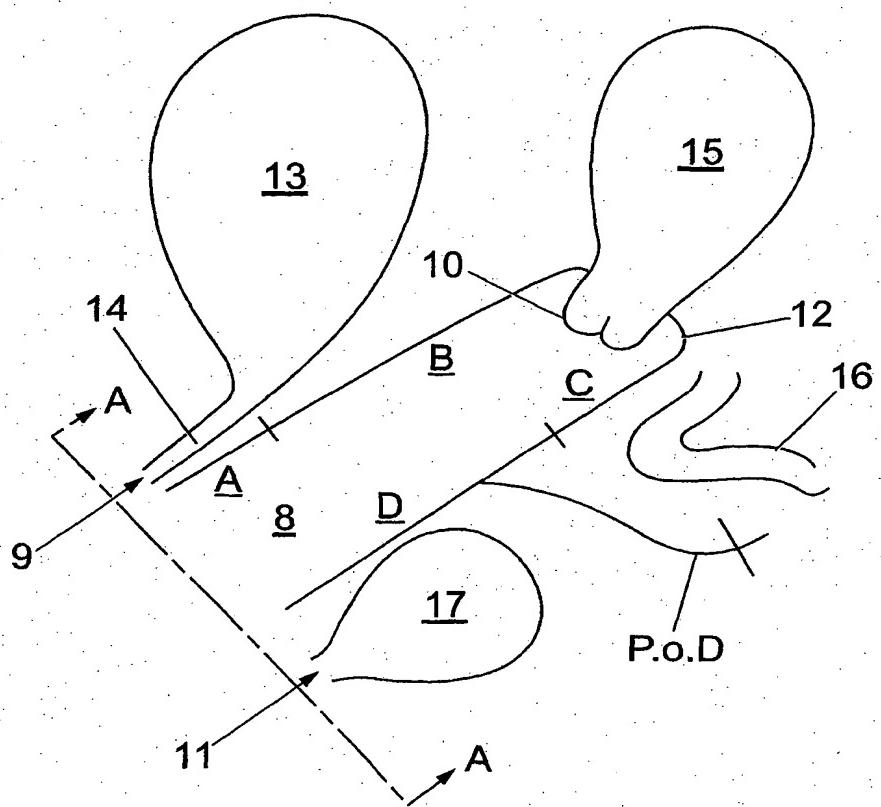


Fig. 6

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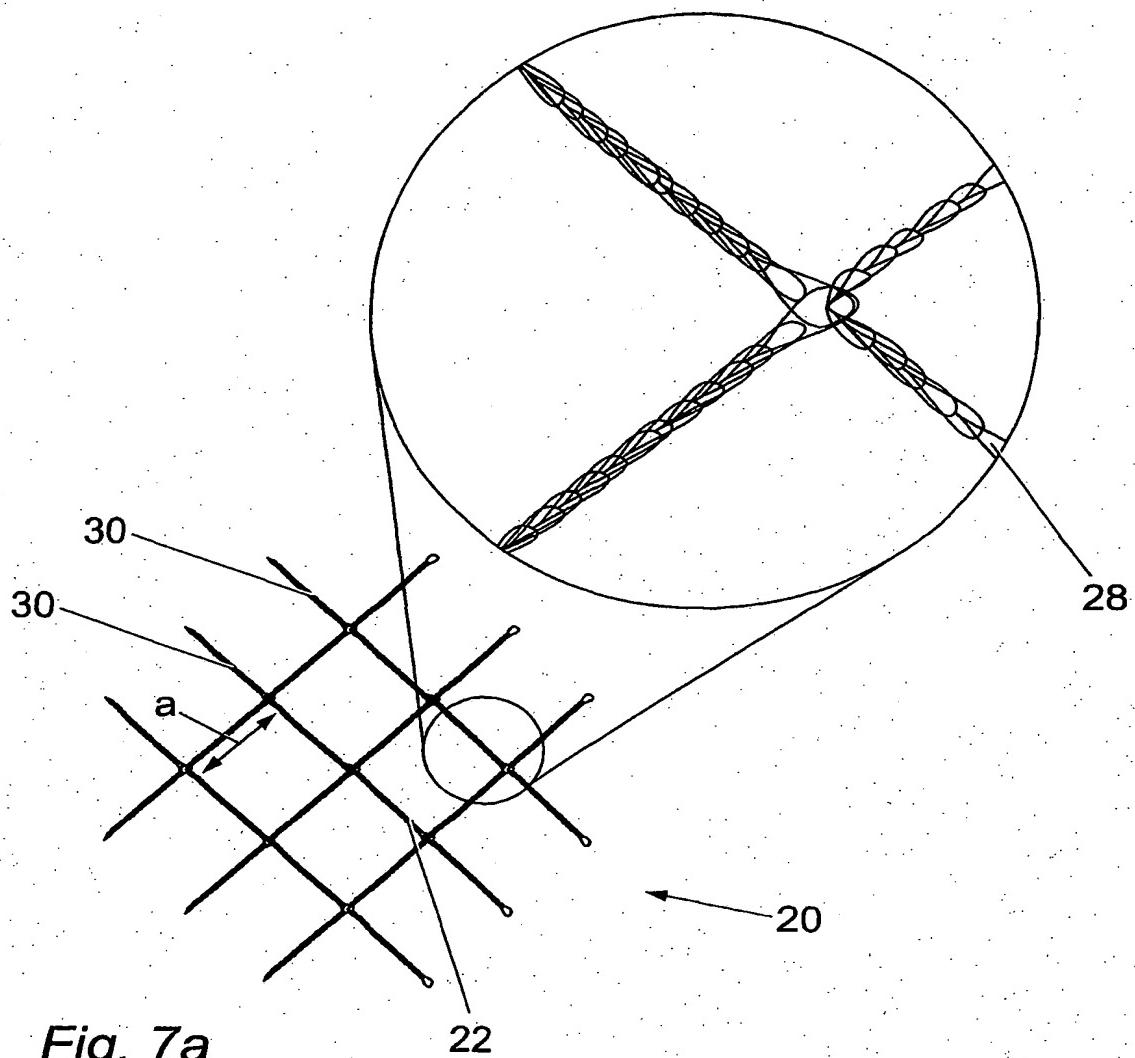


Fig. 7a

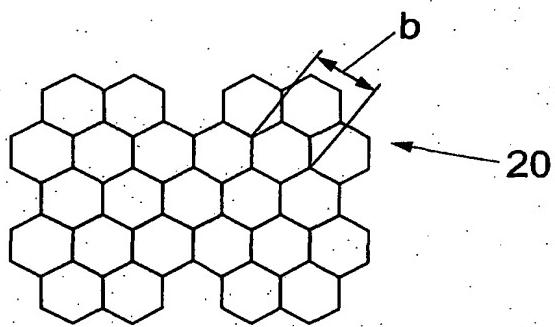


Fig. 7b

6 / 10

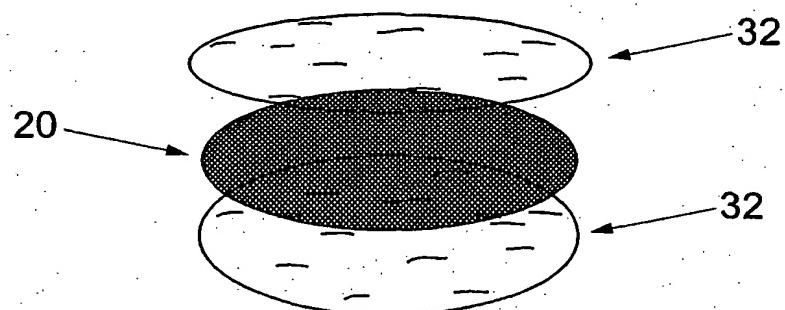


Fig. 8a

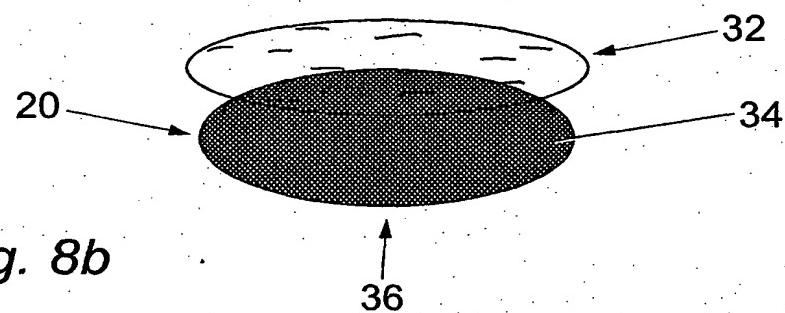


Fig. 8b

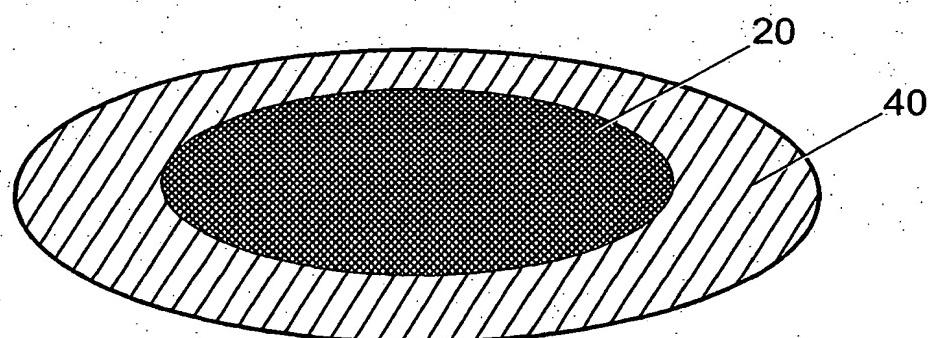


Fig. 8c

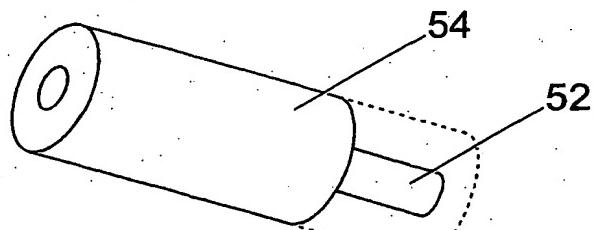


Fig. 8d

7 / 10

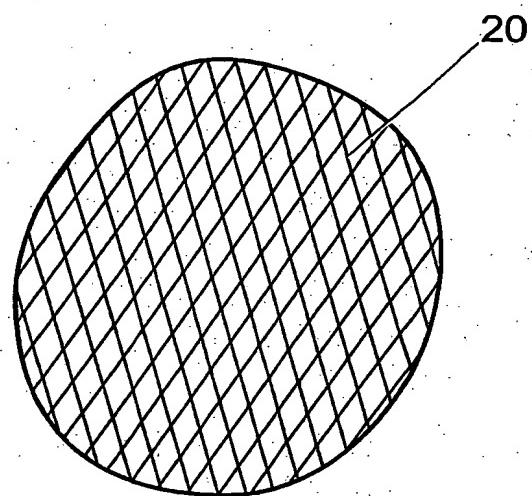


Fig. 9a

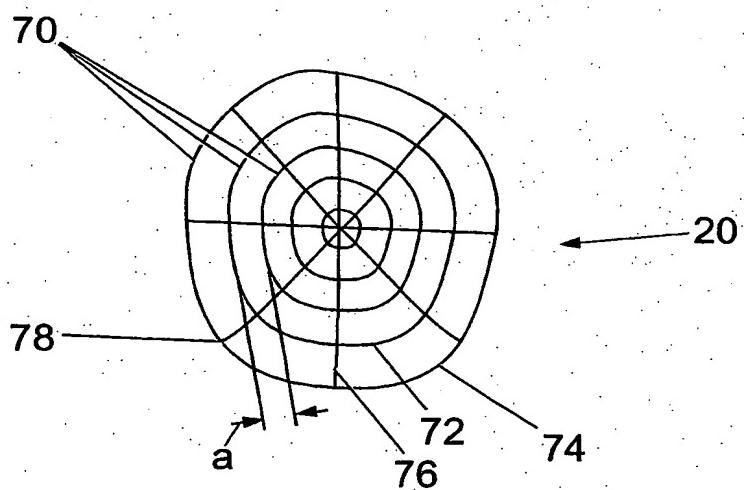


Fig. 9b

8 / 10

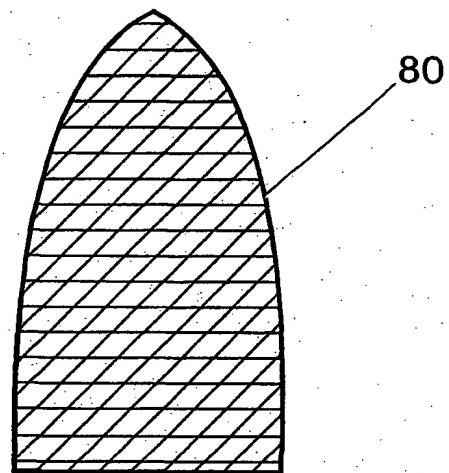


Fig. 9c

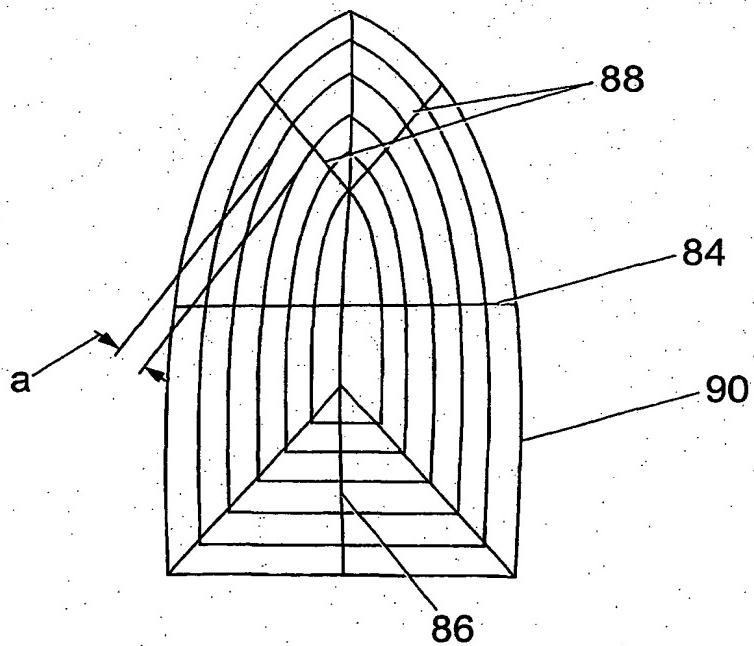


Fig. 9d

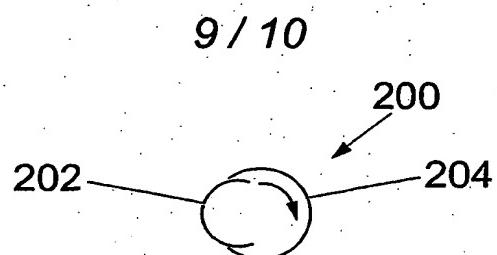


Fig. 10

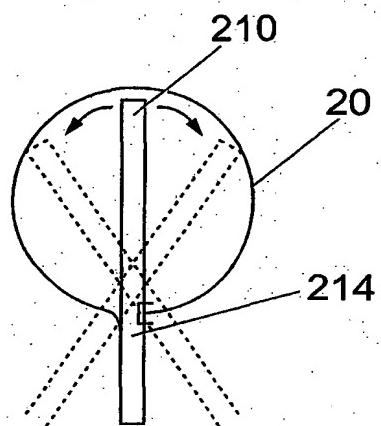


Fig. 11

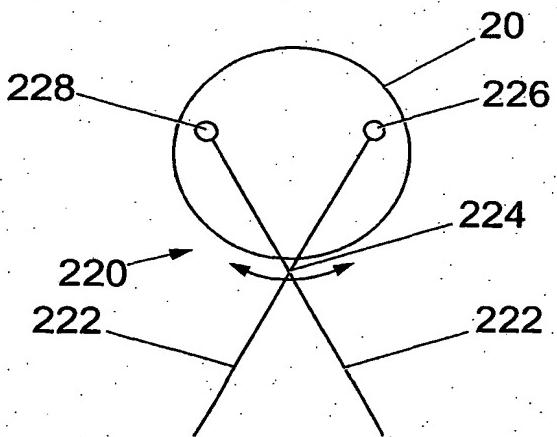


Fig. 12

10 / 10

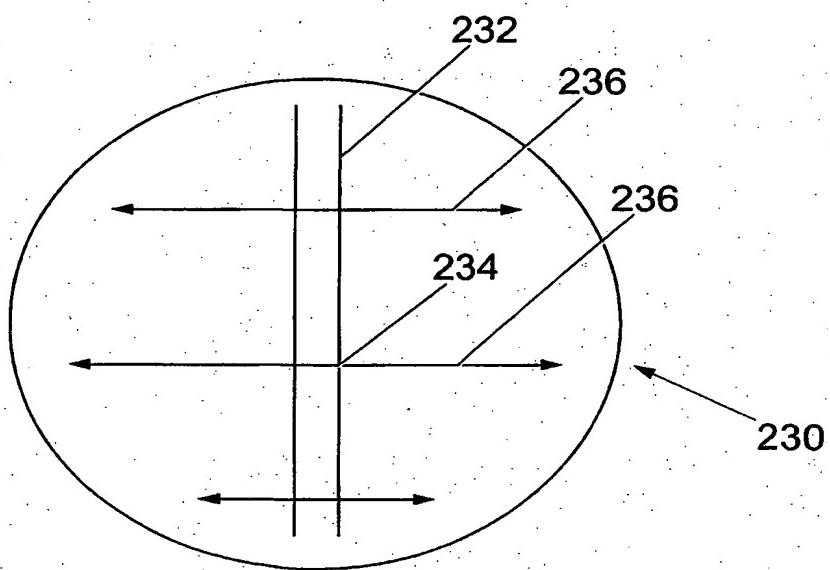


Fig. 13

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 02/01234

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--|--|
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| | page 4, line 1 -page 5, line 32; table | -/- |
| Y | WO 00 07520 A (PELISSIER EDOUARD) 17 February 2000 (2000-02-17) | 15, 38-45, 47-52 |
| A | page 8, line 31 -page 9, line 2; figures | 3,7,16 |
| | | -/- |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

28 May 2002

Date of mailing of the International search report

05/06/2002

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Wolf, C

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 02/01234

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| Y | FR 2 712 177 A (SGRO JEAN CLAUDE) 19 May 1995 (1995-05-19) | 36 |
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| | page 3, line 27 -page 5, line 16; figure 1 | |
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Information on patent family members

International Application No

PCT/GB 02/01234

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